The Health Regulations — what you need to know

Adam Finlay, Partner at McCann FitzGerald, discusses the impact of the Health Regulations recently passed in Ireland

In August 2018, the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations 2018 ('the Regulations') were passed, significantly impacting the processing of personal data in Ireland for health research purposes.

The Regulations impose a number of obligations that apply in addition to generally applicable requirements under the General Data Protection Regulation ('GDPR') and the Data Protection Act 2018 ('DPA 2018'). Most notably, these include that explicit consent must now be obtained from individuals whose personal data are processed for health research purposes (even if this would not be required under the GDPR), except in the limited circumstances that an application not to obtain such consent is approved by a committee ('the Committee') to be established under the Regulations.

All organisations involved in health research in Ireland will need to consider the Regulations and their implications carefully, both for ongoing health research and for intended research in the future. The Regulations have resulted in there being differences between data protection requirements regarding health research in Ireland and in other EU Member States, particularly those where obtaining explicit consent is not a local law requirement.

Scope and impact of the Regulations

The Regulations were made by the Minister for Health, following consultation with the Data Protection Commission, on 7th August 2018 and came into effect on 8th August.

They apply to the processing of personal data for the purposes of 'health research', which is defined as 'scientific research for the purpose of human health'. Regulation 3 specifies types of research within the scope of this definition, which indicate that it is to be construed broadly.

Since the Regulations were made under the DPA 2018, they apply to controllers to whom the 2018 Act applies. In principle therefore, identifying to whom the Regulations apply ought to be clear-cut.

However, the DPA 2018 does not contain any express provisions that state when it applies (e.g. by reference to a controller 'established' in Ireland and processing personal data in the context of that establishment, or to the processing of personal data relating to data subjects who are located in Ireland). As a result, some organisations who are involved in research that is being conducted in Ireland will be faced with uncertainty as to whether the Regulations apply to them, particularly in connection with health research that is being conducted in more than one jurisdiction or involving cross-border collaboration.

Obligations of controllers under the Regulations

Where a controller is processing personal data for 'health research' purposes, it must ensure that certain specified 'suitable and specific measures are taken to safeguard the fundamental rights and freedoms of the data subjects'. These safeguards overlap with, and in some cases go beyond, what is explicitly required under the GDPR and DPA 2018 and include:

- having arrangements in place so that personal data will not be processed in a way that causes, or is likely to cause, damage or distress to the data subject, and that personal data are processed only as necessary to achieve the objective of the health research;
- having appropriate governance structures in place for carrying out the health research, including: ethical Committee approval; specifying who is providing funding for or otherwise supporting the research; specifying what third parties will receive any personal data collected; and providing training in data protection law and practice to those involved in the research; and
- having specified processes and procedures relating to the management and conduct of the research in place, including: carrying out an initial assessment of the data protection implications of the health research and, where required under the GDPR, a Data Protection Impact Assessment; limiting and

logging access to the personal data; and having processes to test and evaluate the effectiveness of security measures adopted to ensure compliance with data protection law.

Notably, the 'suitable and specific measures' required to be taken in these circumstances include a requirement that 'explicit consent' is obtained from the relevant data subjects for the processing of their personal data. This applies except where an application is made to the Committee, and that Committee issues a declaration which will allow the controller to dispense with the otherwise mandatory requirement to obtain explicit consent from the relevant data subject to the processing of their personal data.

This requirement for the collection of explicit consent subject to a limited exception is unusual since, in the absence of the requirement applying as a matter of Irish law, controllers might otherwise be permitted to process personal data for the purposes of health research in compliance with the GDPR without having collected such explicit consent (if they could rely on alternative legal bases to consent under Articles 6 and 9 of the GDPR).

Furthermore, and peculiarly, for the purpose of these Regulations, 'explicit consent' is defined to mean consent obtained in accordance with Article 4 of the GDPR. This is anomalous, since Article 4 of the GDPR sets out the definition of 'ordinary' consent (rather than explicit consent).

> ***"The Regulations do not provide for any grace period for compliance with their other requirements, which came into effect on 8th August (one day after they were made)."***

Health research already underway

For organisations engaged in ongoing health research which began prior to 8th August 2018, the Regulations provide for a transition period for resolving any absence of explicit consent 'as soon as practicable and no later than 30th April 2019'. This may be done either by collecting the required consents from the relevant data subjects, or by applying to the Committee for a declaration that such consents are not required either:

- because the public interest in obtaining explicit consent is significantly outweighed by the public interest in carrying out the research; or
- because the controller obtained consent to the processing of the relevant personal data for health research purposes before 25th May 2018 in compliance with the requirements of Directive 95/46/EC and the Data Protection Acts 1988 and 2003, and such consent was not withdrawn.

Where an application for a declaration is made on the basis of having previously obtained consent from the data subject under the old regime, the controller must demonstrate as part of its application that reasonable efforts were made to contact the data subject for the purposes of re-obtaining their consent.

It is worth noting that this transition period relates to the requirement to have explicit consent for processing (or a declaration from the Committee) only. The Regulations do not provide for any grace period for compliance with their other requirements, which came into effect on 8th August (one day after they were made).

Health research yet to be commenced

A controller who is proposing to process personal data for health research purposes may also apply to the Committee (which has yet to be established) for a similar declaration that explicit consent is not required to be obtained. Such an application can be made on the basis that the public interest in carrying out the health research significantly outweighs the public interest in requiring explicit consent from the data subject. It remains to be seen how this exercise of balancing interests will be conducted in practice, and most likely this will not be clear until the first decisions of the Committee to be established under these Regulations are published.

Any organisation that is considering seeking a declaration that explicit consent is not required will be required to make a detailed written application to the Committee that must include, among other things, a DPIA, confirmation that a Data Protection Officer has been appointed in relation to the research, and confirmation that ethical approval from a recognised research ethics committee has been obtained. In addition, the application must contain certain written information, including information demonstrating that the research requires that the personal data are obtained and processed rather than anonymised data, that the personal data will not be processed in a manner that causes distress, and that no disclosure of personal data will be made unless required by law or the data subject gives explicit consent to the disclosure.

Next steps

Any organisation that is subject to the DPA 2018 and is, or intends to be, involved in health research, should consider whether these Regulations apply and, if they do, review existing data protection measures to ensure that they comply with these new requirements.

(Continued on page 6)

(Continued from page 5)

The Health Research Board has published some helpful guidance regarding the application of these Regulations which can be accessed on its website — hrb.ie. Any gaps in an organisation's measures to comply with these Regulations should be addressed as soon as possible or, in the case of the requirement to obtain explicit consent or a declaration by the Committee that this is not required, by 30th April 2019 at the latest.

Alternatively, organisations who are considering conducting health research in Ireland, but who think it might be impractical to seek explicit consent from the relevant data subjects or to apply to the Committee for a declaration relieving them of this obligation, might consider conducting such research in another jurisdiction which does not impose similar obligations.

There is a concern among some industry stakeholders that these Regulations might make Ireland a less attractive jurisdiction in which to conduct health research than certain other EU Member States. Much will depend on how they are implemented in practice and, particularly, how the Committee exercises its discretion regarding making a declaration that explicit consent is not required in certain circumstances.

Adam Finlay
McCann FitzGerald
Adam.Finlay@mccannfitzgerald.com